



Prairie

EDUCATION & RESEARCH COOPERATIVE

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PROTECT AF

<u>Trial Sponsor:</u>	Aritech
<u>Principal Investigator:</u>	Gregory J. Mishkel, MD
<u>Trial Name:</u>	WATCHMAN Left Atrial Appendage System for Embolic PROTECTION in Patients With Atrial Fibrillation (PROTECT AF)
<u>Purpose:</u>	This is a multi-center, prospective, randomized study, stratified by center, comparing the WATCHMAN device to long term warfarin therapy, demonstrating that the treatment arm is non-inferior to the control arm.
<u>Details:</u>	The WATCHMAN device is designed to be permanently implanted distal to the ostium of the left atrial appendage (LAA) to trap potential emboli before they exit the LAA.
<u>Phase:</u>	Atrial Fibrillation: Phase II Stroke: Phase III
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Prevention, Randomized, Single Blind, Active Control, Single Group Assignment, Safety/Efficacy Study
<u>Expected Enrollment:</u>	500
<u>Study Start:</u>	February 2005

Primary Outcome Measures:

- All stroke
- Systemic embolism
- Cardiovascular death

Secondary Outcome Measures:

- Technical success
- Procedure success
- 30 day major adverse event (MAE)
- Left atrial appendage (LAA) coverage



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Eligibility:

Ages Eligible for Study: 18 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- Patient has paroxysmal, persistent or permanent non-valvular atrial fibrillation (AF)
- Eligible for long term warfarin
- CHADS score ≥ 1 (congestive heart failure [CHF], history of high blood pressure, 75 years of age or older, diabetes, prior stroke or transient ischemic attack [TIA])

Exclusion Criteria:

- Contraindicated for warfarin
- Contraindicated for aspirin or clopidogrel (Plavix)
- CHF Class 4
- Implanted mechanical valve
- Atrial septal or Patent Foramen Ovale (PFO) device
- Platelets $< 100,000$ or hemoglobin < 10
- Left ventricular ejection fraction (LVEF) $< 30\%$